

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : Confirmation No.:  
 Applicant : Etches  
 Filing Date : September 22, 2004  
 Title : Transgenic Aves Producing Human Polyclonal Antibodies  
 Group Art Unit :  
 Examiner :  
 Docket No. : 700603.7/1  
 Customer No. : 34313

Commissioner for Patents  
 PO Box 1450  
 Mail Stop Patent Application  
 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 CFR §§ 1.97 and 1.98, the items identified in this Information Disclosure Statement ("IDS") are brought to the attention of the Office. The items are listed on the attached form PTO-1449. In accordance with the USPTO waiver of the requirement under 37 CFR 1.98(a)(2)(i), only copies of foreign patent documents and non-patent literature are enclosed for the convenience of the Examiner.

The items identified in this IDS may or may not be "material" pursuant to 37 CFR § 1.56. The submission thereof by Applicant is not to be construed as an admission that any such patent, publication or other information referred to therein is material or considered to be material (37 CFR § 1.97(h)), or even qualifies as "prior art" under 35 USC § 102 with respect to this invention unless specifically designated by Applicant as such.

CERTIFICATE OF MAILING (37 CFR §1.8)

I hereby certify, pursuant to 37 CFR §1.8, that I have reasonable basis to expect that that this paper or fee (along with any referred to as being attached or enclosed) would be mailed or transmitted on or before the date indicated with the United States Postal Service with sufficient postage as first class mail on the date shown below in an envelope addressed to Mail Stop Patent Application, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Dated: September 22, 2004

  
 Angela Wendel

DOCSOC1:155236.1

Applicant : Etches et al.  
Appl. No. :  
Examiner :  
Docket No. : 700603.7/1

**INFORMATION DISCLOSURE STATEMENT FILING PROVISION:**

☒ This IDS is believed to be timely in that it is being submitted under 37 CFR § 1.97(b), that is (1) within three months of the filing date of the application, which is not a continued prosecution application filed under § 1.53(d); or (2) within three months of entry of the national stage as set forth in 37 CFR § 1.491; or (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after filing a request for continued examination under § 1.114. Thus, no fee is required.

☒ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and charge the fee due under 37 CFR § 1.17(p) to the deposit account referenced below.

☐ However, if the undersigned is in error in this regard, Applicant respectfully requests that the Office consider this IDS as filed under 37 CFR § 1.97(c), if applicable, and a statement under 37 CFR § 1.97(e) is included below, thus no fee is required.

☐ This IDS is being submitted under 37 CFR § 1.97(c), that is after mailing of a first Office action on the merits, but before a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311.

☐ The fee due under 37 CFR § 1.17(p) is submitted herewith.

☐ A statement under 37 CFR § 1.97(e) is included below, thus no fee is required. In the event that this IDS is not received before a Final Action or a Notice of Allowance, then Applicant respectfully requests that the Office consider the filing of these papers to be submitted under 37 CFR § 1.97(d) and charge the fee due under 37 CFR § 1.17(p) to the deposit account below.

☐ This IDS is being submitted under 37 CFR § 1.97(d), that is after a Final Action under 37 CFR § 1.113 or a Notice of Allowance under 37 CFR § 1.311, but before payment of the issue fee. A statement under 37 CFR § 1.97(e) is included below. The fee due under 37 CFR § 1.17(p) is submitted herewith.

Applicant : Etches et al.  
Appl. No. :  
Examiner :  
Docket No. : 700603.7/1

**STATEMENT UNDER 37 CFR § 1.97(e):**

- ☐ Each item contained in this IDS was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS.
- ☐ No item contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this statement after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this IDS.

**PAYMENT AND/OR AUTHORIZATION TO CHARGE FEES:**

- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above fee(s).
- ☐ Please charge \_\_\_\_\_ to Deposit Account No. **15-0665** for the above fee(s).
- ☒ The Commissioner is authorized to charge any fees required by the filing of these papers, and to credit any overpayment to Orrick, Herrington & Sutcliffe's Deposit Account No. **15-0665**.

Respectfully submitted,

ORRICK, HERRINGTON & SUTCLIFFE LLP

Dated: September 22, 2004

By:   
Kurt T. Mulville  
Reg. No. 37194

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	
				Filing Date	09/22/04
				First Named Inventor	Etches
				Art Unit	
				Examiner Name	
Sheet	1	of	2	Attorney Docket Number	700603.7/1

**U.S. PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	U.S. Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code <sup>2</sup> (if known)		
	AA	5939598 A	08/17/1999	Kucherlapati et al.
	AB	5998209 A	12/07/1999	Jokobovits et al.
	AC	6066778 A	05/23/2000	Ginsburg et al.
	AD	6143559 A	11/07/2000	Michael et al.
	AE	6287863 B1	09/11/2001	Hodgson
	AF	6316600 B1	11/13/2001	Michael et al.

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	T <sup>6</sup>
		Country <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)			
	BA	WO 00/44892 A1	08/03/2000	Tranxenogen, Inc.	
	BB	WO 00/75300 A2	12/14/2000	Transxenogen, Inc.	
	BC	WO 02/12437 A2	02/14/2002	Schooten et al.	

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Examiner Initials <sup>1</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BENEDICT, et al., Inherited Immunodeficiency in chickens: a model for common variable hypogammaglobulinemia in man. Avian Immunology. NY, 1997. pages 197-205	
		BEZZUBOVA et al., Gene conversion in the chicken immunoglobulin locus: a paradigm of homologous recombination in higher eukaryotes. Experientia. 1994, Vol. 50, pages 270-276.	
		CHANH et al., Inherited 7S immunoglobulin deficiency in chickens: presence of suppressor T cells that suppress synthesis of 7S immunoglobulin but not IgM. J Immunol. 1980. Vol. 125, pages 108-114.	
		DAVIES et al., Selection of specific phage-display antibodies using libraries derived from chicken immunoglobulin genes. J. Immunol. Methods. 1995, Vol. 186, pages 125-135.	
		ERICKSON et al., Inherited 7S immunoglobulin deficiency of chickens is associated with bursal degeneration anomalies. Dev & Comp Immunol. 1983. Vol. 6, pages 105-112.	
		FROMMEL et al., Metabolism of G and M immunoglobulins in normal and hypogammaglobulinemic chickens. J Immunol. 1970. Vol. 105, No. 1, pages 1-6.	
		HARVEY et al., Expression of exogenous protein in the egg white of transgenic chickens. Nature biotech. April 2002, Vol. 19, pages 396-399.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicants unique citation designation number (optional). <sup>2</sup>See Kinds of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you are required to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

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PTO/SB/08a (08-03)

Approved for use through 7/31/06. OMB 0651-0031

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<b>Substitute for form 1449A/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	
				Filing Date	09/22/04
				First Named Inventor	Etches
				Art Unit	
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	700603.7/1

		ISHIDA et al., Production of human monoclonal and polyclonal antibodies in transchromo animals. Cloning and Stem Cells. 2002, Vol. 4, No. 1, pages 91-102.	
		IVARIE, R. Avian transgenesis: progress towards the promise. TRENDS in Biotechnology. January 2003, Vol. 21, No. 1, pages 14-19.	
		LOVE et al., Transgenic birds by DNA microinjection. Bio/Technology. January 1994, Vol. 12, pages 60-63	
		MOHAMMED et al. Deposition of genetically engineered human antibodies into the egg yolk of hens, Immunotech. 1998, Vol. 4, pages 115-125.	
		PAIN et al., Long-term in vitro culture and characterisation of avian embryonic stem cells with multiple morphogenetic potentialities. Development. 1996, Vol. 122, pages 2339-2348.	
		SAYEGH et al. Avian B cell development: lessons from transgenic models. Veterinary Immunol. and Immunopath. 1999, Vol. 72, pages 31-37.	
		THORAVALL et al., Germline transmission of exogenous genes in chickens using helper-free ecotropic avian leukosis virus-based vectors. Transgenic Res. 1995, Vol. 4, pages 369-376.	
		VAN DE WATER et al., Inherited dysgammaglobulinemia of chickens: reduced incidence of disease in parabiotic chimeras. Clinical Immunol and Immunopath. 1985, Vol. 36, pages 1-9.	
		VICK et al. Transgenic birds from transformed primordial germ cells. Proc. R. Soc. Lond. 1993, Vol. 251, pages 179-182.	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicants unique citation designation number (optional). <sup>2</sup>See Kinds of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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